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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Marc F. Charette

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ROPES & GRAY LLP

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EXAMINER

WANG, CHANG YU

ART UNIT

PAPER NUMBER

1649

MAIL DATE

DELIVERY MODE

05/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/734,472

Applicant(s)

CHARETTE, MARC F.

Examiner

Chang-Yu Wang

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-32, 34, 43, 44, 46, 48 and 51-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-32, 34, 43, 44, 46, 48 and 51-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION
RESPONSE TO AMENDMENT

Status of Application/Amendments/claims

1. Applicant's amendment filed 1/26/09 is acknowledged. Claims 1-26, 33, 35-42, 45, 47, and 49-50 are cancelled. Claims 27-32, 46, and 48 are amended. Claims 54-60 are newly added. Claims 27-32, 34, 43, 44, 46, 48, 51-53 and newly added claims 54-60 are pending in this application and under examination in this office action.
2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response.
3. Applicant's arguments filed on 1/26/09 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections/Objections Withdrawn

4. The rejection of claims 34 and 35 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement due to new matter is withdrawn in response to Applicant's cancellation of claim 35 and arguments that mature OP-1 comprising aa 293-431 of SEQ ID NO:2 was disclosed by US 5650276 as SEQ ID NO:5, which is incorporated by reference at p. 37, lines 17-21 of the instant specification.

Claim Rejections/Objections Maintained

In view of the amendment filed on 1/26/09, the following rejections are maintained.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-32, 34, 43, 44, 46, 48 and 51-60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for up-regulating the expression of N-CAM and L1 in NG108-15 cells and increasing dendritic arbors of 7-14 DIV cultured hippocampal neurons with OP-1 (BMP-7) protein of SEQ ID NO:2, does not reasonably provide enablement for general methods for reducing spatial or declarative memory dysfunction caused by damaged hippocampal tissues and caused by permanent or transient global ischemia comprising determining the existence of spatial or declarative memory dysfunction and administering OP-1 comprising residues 330-431 of human OP-1 (SEQ ID NO:2). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The rejection is maintained for the reasons made of record.

On p. 7-8 of the response, Applicant argues that amended claims are enabled because the specification has demonstrated OP-1 increases dendritic outgrowth and synaptic development in cultured hippocampal neurons and the specification also describes dendrite density correlates with retention of memory function. Applicant further cites Li et al. (J. Neurosci. Res. 2009, 87:112-22) in support of arguments. Applicant argues that Li teaches that hippocampal neurogenesis induced by fluoxetine

treatment attenuates spatial cognitive deficits induced by ischemic stroke. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, the specification fails to demonstrate that the claimed OP-1 can reduce spatial or declarative memory dysfunction. Although the cited Li reference teaches hippocampal neurogenesis induced by fluoxetine treatment correlates with attenuation of spatial cognitive deficits, neither the specification nor the prior art teaches that relationship between fluoxetine and OP-1. Thus, it is unpredictable whether the effect obtained in fluoxetine treatment in vivo is applicable to the OP-1 treatment in vivo.

In addition, as previously made of record, memory dysfunction or deficit is a complex process and its cause or process is not clear; i.e. it is not only due to neuronal damage or neuronal loss. It is also known in the art that the process of spatial or declarative memory dysfunction is also complex. Based on the prior art and the specification, the instant claims are only enabling for neurite outgrowth or neuronal protection against neuronal damage caused by ischemia or caused by other mechanisms such as malnutrition, anorexia or memory deficit caused by hippocampal neuronal damage or loss. However, the instant claims are not limited to neurite outgrowth or neuronal protection against neuronal damage caused by different mechanisms. The limitation of "spatial or declarative memory dysfunction" is only a general term and is not clear what is encompassed. In addition, an in vitro bioassay in neurite outgrowth is not equivalent to memory recovery and reducing memory dysfunction in vivo because memory dysfunction or recovery involves more than neurite outgrowth or neuronal survival. The specification fails to show that enhancing neurite

outgrowth and neuronal survival by the claimed OP-1 in vitro can really reduce spatial or declarative memory dysfunction in vivo. Thus, it is unpredictable whether the claimed method can truly reduce spatial or declarative memory dysfunction since neither the prior art nor the specification provides any evidence to show that OP-1 is predictably effective in treating undefined and uncharacterized memory dysfunction. Note that

"The 'predictability or lack thereof' in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability. In particular, the court in *In re Marzocchi*, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971)" See MPEP § 2164.03

Accordingly, the rejection of claims 27-32, 34-38, 43, 44, 46, 48 and 51-60 under 35 U.S.C. §112, first paragraph, because the specification does not enable the invention commensurate in scope with the claims is maintained.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27-32, 34-38, 43, and 44 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6407060. The rejection is maintained for the reasons made of record.

On p. 11 of the response, Applicant requests the ODP rejection be held in abeyance until allowable subject matter is found. The rejection of claims under obviousness double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6407060 is maintained of record until a terminal disclaimer is filed. It is noted that traversal at the time of indication of allowable subject matter will not be considered timely.

Conclusion

7. NO CLAIM IS ALLOWED.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday from 8:30 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/
Chang-Yu Wang, Ph.D.
May 19, 2009

/Christine J Saoud/
Primary Examiner, Art Unit 1647